DETAILED ACTION

Responsive to communications entered 10/5/2007. Claims 1-16 are pending. Claims 1-6,14-16 are withdrawn. Claims 7-13 are under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

Applicant's election with traverse of Group II (Claims 7-13) in the reply filed on 05/0/2006 is again acknowledged.

Applicant has elected with traverse the following species for the elected invention group II (Claims 7-13) in the reply filed on 05/08/2006.

(a) For the single specific species of hapten, applicant elected "biotin."

(b) For the single specific species of reporter molecule, applicant elected "horseradish peroxidase."

Upon further consideration the species election regarding a reporter molecule, is hereby withdrawn.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the prior application and in the later-filed application must be sufficient to comply with the

requirements of the first paragraph of 35 U.S.C. 112. See Transco Prods., Inc. v. Performance Contracting, Inc., 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994) [taken from MPEP 201.01]

The instant application has a filing date of 9/30/2003 and claims priority to provisional application 60415119 filed 9/30/2002. Nevertheless, support for the alignment mark is formed by a MAS™ instrument as set forth in claim 7c, is not disclosed in the provisional application. See also 35 USC 112 first paragraph "new matter" considerations below.

Therefore 9/30/2003 is the date for the purposes of prior art concerning claims 7-13.

Response to Arguments

Applicant's arguments concerning support for "subarrays" in provisional application 60415119, as set forth in the reply entered 10/5/2007 p 5 are persuasive, however the priority date for the purposes of prior art remains 9/30/2003, in view of the lack of support for the amendment concerning the alignment mark is formed by a MAS™ instrument.

Oath/Declaration

The new declaration is acceptable.

Specification/Drawing

The replacement drawing for figure 1 was received on 1/16/2008. This drawing is acceptable.

Withdrawn Objection(s) and/or Rejection(s)

The rejection of claims 8, 11-12 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is hereby withdrawn in view of applicant's amendments to the claims.

The rejection of claims 7, 8,11,12 and 13 under 35 U.S.C. 102(b) as being anticipated by **Noblett** (US Patent 6362004) is hereby withdrawn in view of applicant's amendments to the claims.

The rejection of claims 7-13 under 35 U.S.C. 103(a) as being unpatentable over **Noblett** (US Patent 6362004) in view of **Zhu et al** (US Patent 6936416) is hereby withdrawn in view of applicant's amendments to the claims.

New Claim Rejection(s) – 35 USC § 112

The following is a quotation of the **first** paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection concerns "new matter."

This rejection is necessitated by Applicant's amendment to the claims.

Claim 7c has been amended insert "the alignment mark is formed by the same MAS™ instrument used to build the probe sets of step b." It is noted however, especially in accordance with paragraph 0011 of the present published application, that the alignment mark, when comprising biotin as a hapten requires off-line deprotection. Paragraph 0011 states "The array is **removed from the instrument** and deprotected (since the biotin and the array are **not functional until deprotected**..." Emphasis added. In other words, removal of the dimethoxytrityl group, shown in figure 1 is not possible with the MAS™ instrument alone and the array must removed to be functional, therein, absent evidence to the contrary, the alignment mark can not be formed by the MAS™ instrument in of itself.

Applicants are reminded that it is their burden to show where the specification supports any amendments to the disclosure. See MPEP 714.02, paragraph 5, last sentence and also MPEP 2163.06 I.

MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should

conclude that the claimed subject matter is not described in that application. MPEP 2163.06 further notes "When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. *Applicant should therefore specifically point out the support for any amendments made to the disclosure*.

The following is a quotation of the **second** paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This rejection is necessitated by Applicant's amendment to the claims.

Claims 7 and 11 recite the "MAS™ instrument."

According to MPEP 2173(u): If the trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of the 35 U.S.C. 112, second paragraph. Ex parte Simpson, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. In fact, the value of a trademark would be lost to the extent that it became descriptive of a product, rather than used as an identification of a source or origin of a product. Thus, the use of a trademark or trade name in a claim to identify or describe a

material or product would not only render a claim indefinite, but would also constitute an improper use of the trademark or tradename.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 7-11,13 are rejected under 35 U.S.C. 102(b) as being anticipated by **Singh-Gasson et al** (1999 Nature Biotechnology 17:974-978).

This rejection is necessitated by Applicant's amendment to the claims.

The claimed subject matter per claim 7 is drawn to a method for making a microarray having a plurality of subarrays surrounded by a visible or machine readable alignment mark in an interstitial region of the microarray, the method comprising the steps of:

a) selecting at least one probe set comprising probes of interest,
b) building the probe sets on a microarray to provide a plurality of subarrays, wherein the probe sets are built with a MAS^{TM} instrument; and
c) depositing a hapten and an illuminating compound around the plurality of subarrays to form the alignment mark on the interstitial region of the microarray, wherein the alignment mark is formed by the same MAS^{TM} instrument used to build the probe sets of step b).

Claims 8-11,13 represent variations thereof.

Singh-Gasson et al teach, throughout the document, and especially the title, and figure 1 synthesis of oligonucleotide microarrays using a maskless array synthesizer (MAS) comprising a digital micromirror array (DMD).

Singh-Gasson et al teach in the paragraph bridging p 975 and 976, an oligonucleotide probe set from *Arabidopsis thaliana* Calmodulin-like Protein Kinase (CPK) genes, which is taken as "selecting at least one probe set comprising probes of interest," as set forth in claim 7a. Singh-Gasson et al teach in figure 5, subarrays comprising building said CPK probe set(s) built with said MAS, as set forth in claim 7b. Singh-Gasson et al further teach in figure 5, deposition of biotin, which is taken as "depositing a hapten" of claim 7c. Singh-Gasson et al teach in figures 4 and 5, illuminating compounds including fluorescein and streptavidin phycoerythrin, the former of which, in figure 4, is deposited in a border region of an array, reading on "depositing...an illuminating compound around the plurality of subarrays to form the alignment mark on the interstitial region of the microarray, wherein the alignment mark is formed by the same MAS™ instrument used to build the probe sets of step b)," as set forth in claim 7c.

Said biotin reads on the biotin hapten of claim 8.

Said streptavidin phycoerythrin is taken as the streptavidin conjugated to a dye reporter molecule, set forth in claims 9-10.

Said fluorescein is added to the array shown in figure 4 by photopatterning a fluorescein phosphoramidite following photolysis (deprotection) of the (R,S)-1-(3,4-(methylenedioxy)-6-nitrophenyl)ethyl chloroformate (MeNPOC) protecting group, as set forth in claim 11.

Said border deposited with fluorescein surrounding the array shown in figure 4 of Singh-Gasson et al is taken as the alignment mark is precisely placed immediately

adjacent to and surrounding the subarray as set forth in claim 13. Singh-Gasson et al demonstrate in figure 3, various high resolution patterns made with the MAS and visualized with fluorescein, which is taken as providing "an alignment mark which is flexibly deployable within the array...," as set forth in claim 13.

New Claim Rejection(s) – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 7-11,13 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Singh-Gasson et al** (1999 Nature Biotechnology 17:974-978) in view of **Giegrich et al** (1998 Nucleosides & Nucleotides 17:1987-1996).

This rejection is necessitated by Applicant's amendment to the claims.

Singh-Gasson et al is relied on as above.

Singh-Gasson et al do not teach the 2-(2 nitrophenyl)-propoxycarbonyl protecting group (NPPOC) for the phosphoramidite set forth in claim 12.

Giegrich et al teach, throughout the document and especially tables 1, 2 and scheme 2 a comparison of NPPOC and MeNPOC protecting groups for nucleoside phosphoramidites with regard to half life.

It would have been *prima facie* obvious for one of ordinary skill in the art, at the time the claimed invention was made to substitute the MeNPOC protecting group, in the synthesis of oligonucleotide microarrays using a maskless array synthesizer (MAS) per Singh-Gasson et al, for the NPPOC advocated by Giegrich et al.

One of ordinary skill in the art would have been motivated to make the substitution of the MeNPOC protecting group, in the synthesis of oligonucleotide microarrays using a maskless array synthesizer (MAS) per Singh-Gasson et al, for the NPPOC advocated by Giegrich et al because NPPOC showed a significant improvement in half life of only 40 seconds versus 2.5 minutes for MeNPOC, as noted by Giegrich et al on p 1988, last paragraph, which have generated better quality microarrays in less time.

Furthermore, the substitution of NPPOC for MeNPOC per Singh-Gasson et al represents substituting equivalents known for the same purpose (i.e. photolabile protecting groups), a basis for obviousness according to MPEP 2144.06.

One of ordinary skill in the art would have had a reasonable expectation of success in combining the NPPOC protecting group of Giegrich et al with the maskless

array synthesizer of Singh-Gasson et al because both are interested in oligonucleotide synthesis, thus the NPPOC protecting group of Giegrich et al lies well with in the scope of DNA microarrays prepared by DMD technology according to Singh-Gasson et al.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Gross whose telephone number is (571)272-4446. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, J. Douglas Schultz can be reached on 571 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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